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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,762	03/19/2001	Virginia Goss Tusher	M-10523 US	8102

36257 7590 10/12/2006

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,762	Applicant(s) TUSHER ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 28-30, 33, 44, 46, 58, 60, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 28-30, 33, 58, 60, 65 and 66 is/are rejected.
- 7) ☒ Claim(s) 44 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 21 August 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-22, 28-30, 33, 44, 46, 58, 60, 65, and 66 are currently pending. Claims 23-27, 31, 32, 34-43, 45, 47-57, 59, and 61-64 have been cancelled.

Claim Objections

Claims 1, 28, 44, 46, 58, 60, 65, and 66 are objected to for the following informalities:

The claims, as amended, recite "said expected values being indicative of extent of variations". This phrase is grammatically incorrect and should read, "said expected value being indicative of the extent of variation". Correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22, 28-30, 33, 58, 60, 65, and 66 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that the claims, as amended, overcome the outstanding rejections by “deriving or providing an expected value of the parameter, wherein the expected value is indicative of extent of variations in the parameter introduced by the data collection process itself”. Further, Applicant contends, “this results in better success rate of detecting *bona fide* changes in gene expression and a reduced false discovery rate in the examples described in the present application”.

This is not persuasive, as the claims do not produce a result which is concrete, tangible, and useful, as written. The values may be indicative of extent of variations, however, the values are not in a tangible form such that a useful result is “produced” that is useful to one of skill in the art. A better success rate does not overcome the rejections of the claims, as a “better success rate” does not provide a concrete, tangible, or useful result.

2. Applicant argues that “the various claim elements in the rejected claims do not merely manipulate abstract concepts or data, but the associated values that are manipulated correspond to useful, concrete, and tangible things-the levels of mRNA or levels of protein. These levels may be indicative of significant biological characteristics or activity. As clearly described in the specification, such biological characteristics or activity may, for example, be caused by the effect of radiation on genes, by inducing or repressing gene expression”.

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This is not persuasive, as the instant claims do not recite that the instant values correspond to levels of mRNA or protein that indicate significant biological activity or characteristics that may be caused by a certain effect, such as radiation. In contrast, the claims are directed to analyzing a plurality of sets of values through a series of steps and providing a list of genes whose values differ. This does not constitute a concrete, tangible, and useful result under 35 USC 101 (see Interim Guidelines of November 2005), as no tangible result is provided such that would be useful one of skill in the art.

The claims above remain rejected.

The rejections over claims 44 and 46 have been withdrawn, as the claims provide for a computer readable storage device embodying a computer program of instructions executable by a computer.

Conclusion

No claims are allowed.

The outstanding rejections under 35 USC 101/Utility have been withdrawn in view of Applicant's arguments and submission of article with the response.

The outstanding rejections under 35 USC 112, 1st paragraph/Written Description have been withdrawn in view of Applicant's arguments.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

October 1, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow
Patent Examiner